Remarks

Claims 1-77 are pending in the application and are subject to a restriction requirement. Restriction between Groups 1 to 9, characterized by the examiner as:

Group 1. Claims 1-27, 32-38, 69, 76 and 77, drawn to compounds, processes for making and methods of using the compounds, classified in class 514, subclass 355+.

Group 2. Claims 28[1]-31 and 39, drawn to a conjugate, and compositions and methods of treatment thereof classified in class 514, subclass 355+.

Group 3. Claims 40-54 drawn to a method of reducing or eliminating the effects of inonizing radiation, classified in class 514, subclass 355+.

Group 4. Claims 55-68 drawn to a method of protecting an individual from cytotoxic side effects, classified in class 514, subclass 339+.

Group 5. Claims 70 and 75 drawn to a compound of formula II and a process of making the same, classified in class 564, subclass 355+.

Group 6. Claim 71 drawn to a compound of formula II and a process of making the same, classified in class 546, subclass 315+.

Group 7. Claim 72 drawn to a process of making the compound of formula Iz, classified in class 568, subclass 63+.

Group 8. Claim 73 drawn to a process of making the compound of formula IV, classified in class 546, subclass 315+.

Group 9. Claim 74 drawn to a process of making the compound of formula V, classified in class 546, subclass 315+.

Applicants elect Group 1. Applicants also traverse, and request reconsideration of, the restriction requirement.

The examiner states that unity is lacking because: "[t]here is no special technical feature, which unites the groups"; (2) "even if there were a special technical feature there must be unity of invention also"; and (3) "groups 1-9 together do not meet the requirement of unity of invention as given ... in [subparagraphs] (1)-(5) [of 37 C.F.R. § 1.475(b)]."

[1] The office action refers to Group 2 as comprising "Claims 27-31 and 39". It is assumed that what is meant is "Claims *28*-31 and 39", since claim 27 is already grouped in Claim 1.

MPEP 1893.03(d) reminds examiners that "unity of invention (not restriction) practice is applicable in ... national stage applications submitted under 35 U.S.C. 371." Under the decision in *Caterpillar Tractor Co. v. Com'r Pat. & Trademarks*, 650 F.Supp. 218 (E.D. Va. 1986), unity of invention must be determined under the provisions of the Patent Cooperation Treaty in a national stage application filed under 35 U.S.C. § 371. Therefore the examiner must make any restriction requirement in accordance with the PCT, the PCT rules (specifically Rule 13) and the Administrative Instructions under the PCT. It is not proper for the examiner to assume that lack of unity would occur in a situation where restriction could properly be made in a non-PCT application.

The examiner misstates the legal standard for unity of invention in at least two ways: first by incorrectly stating that there are two separate requirements for unity of invention (a special technical feature plus unity of invention), and second by incorrectly stating that the requirements for the separate unity of invention requirement are "given in" 37 C.F.R. § 1.475(b).

Under the standard for unity of invention in a national stage applications submitted under 35 U.S.C. § 371, the presence of a special technical feature linking the claims is sufficient to satisfy the unity of invention requirement. As 37 C.F.R. § 1.475(a) explicitly states "the requirement of unity of invention *shall be fulfilled ... when there is a technical relationship* among those inventions *involving one or more of the same or corresponding special technical features.*" The presence of a special technical feature linking the claims thus defines, rather than being an additional requirement to, the unity of invention standard.

The examples quoted in subparagraphs (1)-(5) of 37 C.F.R. § 1.475(b) do not define unity of invention. 37 C.F.R. § 1.475(b) states that "a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the ... combinations of categories" defined in subparagraphs (1)-(5). The examiner will note that while 37 C.F.R. § 1.475(b) does present situations where the unity of invention requirement "will be considered" to be met, the regulation does *not* state that unity of invention is *only* satisfied in the situations presented in subparagraphs (1)-(5). The examiner is

therefore incorrect in stating that the claim groups do not meet the "requirement of unity of invention as given in" subparagraphs (1)-(5) of 37 C.F.R. § 1.475(b). Rather, a definition of "unity of invention" is given in 37 C.F.R. § 1.475(a), and under that definition the "unity of invention" requirement is satisfied when there is one or more special technical features linking the claims.

Under unity of invention practice, an applicant has the "right to include in a single application ... those inventions which are so linked as to form a single general inventive concept." MPEP 1893.03(d). As explained above the requisite unity of invention is present where there is one or more special technical features linking the claims. *See* 37 C.F.R. § 1.475(a). Therefore, restriction in an application filed under 35 U.S.C. § 371 may not properly be required between groups of claims that are "linked as to form a single general inventive concept", i.e. groups of claims that have a linking special technical feature.

The examiner has improperly required restriction among groups of claims that do not lack unity under the unity of invention standard. Specifically, the special technical feature that links all claims are the compounds of Formula I, as defined by claim 1.

The restriction requirement made is improper insofar as restriction has been required between Groups 1, 3 and 4. The claims of Group 1, 3 and 4 relate to novel compounds (Group 1: the compounds of Formula **I** in claim 1) and two methods of use of those compounds (Groups 3 – method of eliminating effects of ionizing radiation; and Group 4 – method of protection from ionizing radiation).

Claims for products and for uses of the product are explicitly recognized as satisfying the unity of invention standard in the Administrative Instructions for determining unity of invention under the PCT (Administrative Instructions under the PCT, Annex B, para. (e)(i)), as well as by the MPEP 1850(III)(A), and the Patent Office Rules (37 C.F.R. § 1.475(b)(3)). The compounds of Formula **I** are clearly a special technical feature linking Group 1 on the one hand and Groups 3 and 4 on the other hand.

The restriction as between Groups 1, 3 and 4 is also improper to the extent it ignores claim dependencies. All of the claims of Groups 3 and 4 depend directly or indirectly from claim 1 (Group 1). Claim dependency is a basis for unity of invention. *See* Administrative Instructions under the PCT, Annex B, para. (c)(i) ("If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims"). Therefore there must be unity of invention between Groups 1, 3 and 4.

Unity of invention also exists as regard to Group 2, since the compounds of Formula **I**, as defined by claim 1, again are a unifying special technical feature. The structure of the antibody conjugates of Group 2 comprises a compound of claim 1 linked to an antibody. The claims to the antibody conjugates of Group 2 are clearly part of the same general inventive concept as the claims to the compounds per se of Group 1, and their medical use. The antibody conjugates connect the compounds of Formula I (claim 1) to an antibody in order to target the delivery of the compound of Formula I to the appropriate site in the body, but, nevertheless, the useful therapeutic utility of the conjugate arises because of the incorporation of the compound of Formula I as an essential structural element which imparts the desired activity. The Formula I structure is therefore a technical feature unifying the antibody conjugates of Group 2 with the compounds of Group 1.

The restriction requirement is also improper to the extent it ignores the dependency of the Group 2 claims on the claims of Group 1. Each of the claims of Group 2 depends directly or indirectly from claim 1.

The restriction as it relates to Group 5 and Group 6 is also improper. Group 5 comprises claims 70 and 75. Group 6 comprises claim 71. Claim 75 is directed to the novel intermediate of Formula II, used in the preparation of a subgenus of the compounds of Formula I, namely, the subgenus defined by Formula Ie in claim 3. Claim 70 is directed to a process for preparing that subgenus of compounds, starting from the further upstream intermediate of Formula IIA. Claim

71 depends from claim 70 and recites a method by which the starting material of claim 70 (the Formula IIA compound) is made.

The novel compounds of Formula I are special technical features linking the claims of Group 1 and the intermediate of claim 75. Specifically, the compound of Formula II (claim 75) is an intermediate used in the synthesis of a subgenus of the compounds of Formula I, namely the compounds of Formula Ie of claim 3. As the Administrative Instructions explain:

> (ii) Unity of invention shall be considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:
>
> (A) the intermediate and final products have the same essential structural element, in that:
>
> ... (2) the chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product, and
>
> (B) the intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

Administrative Instructions under the P.C.T., Annex B, para. (g)(ii). *See also* MPEP 1850(III)(C).

Unity of invention is present as between the intermediate of Formula II (claim 75) and Group I because the intermediate incorporates a structural element into the final compound of claim 3, namely the structure in common between Formula II in claim 75 and Formula Ie in claim 3. The compounds of Formula Ie are separated from the compounds of Formula II by a small number of intermediates. Specifically, the compounds of Formula II are converted to the compounds of Formula Ie by reaction with a compound of Formula III (*see* the scheme set forth in claim 69).

Unity of invention is also present as between Group 1 and claim 70 of Group 5, in that the process of claim 70 defines a method for making the intermediate (Formula II compound) used in the aforementioned scheme for the synthesis of the claim 3 (Formula Ie) compounds. Unity of invention is present also as to claim 71, since that claim depends from claim 70, and

recites a further feature thereof, namely a prepartion method for the starting material of the claim 70 method, i.e., the Formula IIA compounds.

Furthermore, the restriction as to claim 70 (Group 5) and claim 71 (Group 6) is improper in that both claims depend directly or indirectly from claim 69, which itself is grouped in Group I. Claims 70 and 71 further limit the process as defined in claim 69 by reciting further steps. As indicated above, claim dependency is a basis for unity of invention. *See* Administrative Instructions under the PCT, Annex B, para. (c)(i).

In conclusion, there is unity of invention between Group 1, and Group 5 and 6.

The restriction requirement is also improper as to Groups 7 (claim 72) and 8 (claim 73). Claim 72 is directed to a method for the preparation of the compounds of Formula Iz (claim 2). The latter comprise a subgenus of the compounds of Formula I (claim 1). Claim 73 depends from claim 72, and recites the upstream step by which the starting material of claim 72 (the Formula IV compound) is made.

Unity of invention is present as between Group 1 and Groups 7 (claim 72) and 8 (claim 73) in that the process of claim 72 defines a method for making the compounds of claim 2. As indicated above, unity is present as between a product and a method of its production. Unity of invention is present also as to claim 73, since that claim depends from claim 72, and recites a further feature thereof, namely a prepartion method for making the starting material of the claim 72 method, i.e., the Formula IV compounds.

Unity of invention as between Group I, and Groups 7 (claim 72) and 8 (claim 73), is also apparent from claim dependency. Claims 72 and 73 depend directly or indirectly from claim 2, which is grouped in Group 1. Thus, because of claim dependency, unity of invention is present between Group 1, and Groups 7 and 8. *See* Administrative Instructions under the PCT, Annex B, para. (c)(i).

The restriction requirement is improper as it relates to Group 9. Unity of invention is present as between Group 1 and Group 9 (claim 74). Claim 74 defines a method of using the sulfoxides of Formula I (claim 1) in the production of the corresponding sulfones. Claim 1 and

claim 74 are related as product and method of use. Claims for products and uses thereof satisfy the unity of invention standard (Administrative Instructions under the PCT, Annex B, para. (e)(i)), as well as by the MPEP 1850(III)(A), and the Patent Office Rules (37 C.F.R. § 1.475(b)(3)). Thus, the compounds of Formula I are clearly a special technical feature linking Group 1 on the one hand and Groups 9 on the other hand.

In summary, the novel compounds of Group I comprise a special technical features that link each of Groups 1 to 9. The claims are all directed to a single general inventive concept, namely the compounds of Group I, methods of treatment using them, processes for making them, intermediates that are useful in making them, and methods for using them as starting materials in the production of other compounds.

Because of the special technical features linking the groups of claims, and since the groups of claims all relate to a single general inventive concept, contrary to the examiner's assertion, unity of invention is clearly present as between Groups 1 to 9. The examiner is therefore respectfully requested to withdraw the restriction requirement and proceed expeditiously to examining the application on the merits.

Respectfully submitted,

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